



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,521	06/10/2005	John Spencer Cook	PG4793USw	7811

23347 7590 09/04/2008

GLAXOSMITHKLINE
CORPORATE INTELLECTUAL PROPERTY, MAI B482
FIVE MOORE DR., PO BOX 13398
RESEARCH TRIANGLE PARK, NC 27709-3398

EXAMINER

SHTERENGARTS, SAMANTHA L

ART UNIT	PAPER NUMBER
----------	--------------

1626

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

09/04/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USCIPRTP@GSK.COM
LAURA.M.MCCULLEN@GSK.COM
JULIE.D.MCFALLS@GSK.COM

Office Action Summary	Application No. 10/509,521	Applicant(s) COOK ET AL.	
	Examiner Samantha L. Shterengarts	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 14 and 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 14 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>28 September 2004</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1626

DETAILED ACTION

Priority

1. The instant application is a national stage entry of PCT/EP03/03345, filed March 27, 2003, which claims foreign priority to Patent No. GB 0207432.6, filed March 28, 2002. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on September 28, 2004 was in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.98. The IDS document was considered. A signed copy of form 1449 is enclosed herewith.

Election/Restrictions

3. Upon further consideration of Applicant's arguments in the reply filed July 1, 2008, and the cancellation of claims 11-13, which lacked unity of invention, the restriction requirement mailed April 1, 2008, is withdrawn. Claims 1-10, 14, and 15 are currently pending in the instant application and will be examined on their merits.

Specification

4. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without

Art Unit: 1626

underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Content of Specification

- (a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.
- (b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.
- (c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.
- (d) The Names Of The Parties To A Joint Research Agreement: See 37 CFR 1.71(g).
- (e) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence

Art Unit: 1626

Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.

- (f) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:
- (1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."
 - (2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."
- (g) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.
- (h) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.
- (i) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.

Art Unit: 1626

- (j) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).
- (k) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).
- (l) Sequence Listing: See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

Claim Rejections - 35 USC § 112

(First Paragraph)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 9 and 14-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of asthma and rhinitis, does not reasonably provide enablement for treatment of any inflammatory condition, or prevention of any inflammatory condition. The specification does not enable any person skilled in the art to which

Art Unit: 1626

it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The Nature of the Invention

The claimed compound of formula (I) are CCR3 antagonists and eosinophil inhibitors (eosinophils are inflammatory mediators). The prophylaxis or “prevention” actually means to anticipate or counter in advanced, to keep from happening, etc. and there is no disclosure as to how one skilled in the art can reasonably establish the basis and the type of subject to which the instant compounds and compositions can be administered in order to have the "preventive" effect for “a human or animal subject suffering from or **susceptible to** an inflammatory condition.” Furthermore, instant claim 9 is drawn to the treatment and prevention (implied by "susceptible to" language) of a variety of diseases. Some of these diseases are known to exist and some may be discovered in the future, and for those there is no enablement provided.

The State of the Prior Art and the Predictability or lack thereof in the art

The state of the prior art is that the pharmacological art involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat which specific diseases by what mechanism). There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

The instantly claimed invention is highly unpredictable as discussed below: It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually

Art Unit: 1626

assessed for physiological activity. In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instantly claimed invention is highly unpredictable since one skilled in the art would recognize that in regards to therapeutic and preventive effects of the above listed diseases, whether or not the disease is affected by the instantly claimed compounds.

With regards to methods of treating and preventing inflammatory disorders, the diseases are too divergent and require different methods of treatment. Examples of disorder associated with inflammation include, but are not limited to: autoimmune diseases, chronic inflammation, chronic prostatitis, glomerulonephritis, hypersensitivities, inflammatory bowel diseases, pelvic inflammatory disease, reperfusion injury, rheumatoid arthritis, shoulder tendonitis, transplant rejection, vasculitis, and various allergies. This broad list of diseases each has a different cause, and for the majority of the list, a different treatment. There is not one class of compounds, let alone one compound, which can treat/prevent all of these diseases.

Each specific inflammatory disease is associated with different and often multiple mediators with redundant effects. For example, there have been more than 100 mediators identified for asthma (Barnes, P.J., Pharmacological Reviews, Vol. 56, No. 4, p. 517). Barnes states that “blocking a single mediatory when so many are involved and with redundant effects, it is unlikely that this approach will product major clinical benefit...the only way to determine the importance of a mediator is to study the effect a specific inhibitor in the disease, and this will require careful and prolonged clinical studies” (Barnes, P.J., Pharmacological Reviews, Vol. 56, No. 4, p. 541).

Art Unit: 1626

For a compound or genus to be effective against inflammation generally is contrary to medical science. Inflammation is a process, which can take place individually in any part of the body. There is a vast range of forms that it can take, causes for the problem, and biochemical pathways that mediate the inflammatory reaction. There is no common mechanism by which all, or even most, inflammations arise. Accordingly, treatments for inflammation can normally be tailored to the particular type of inflammation present, as there is no, and there can be no, "magic bullet" against inflammation generally. Inflammation is the reaction of vascularized tissue to local injury; it is the name given to the stereotyped ways tissues respond to noxious stimuli. These occur in two fundamentally different types. Acute inflammation is the response to recent or continuing injury. The principal features are dilation and leaking of vessels. Chronic inflammation or "late-phase inflammation" is a response to prolonged problems, orchestrated by T-helper lymphocytes. It may feature recruitment and activation of T- and B-lymphocytes, macrophages, eosinophils, and/or fibroblasts. The hallmark of chronic inflammation is infiltration of tissue with mononuclear inflammatory cells. Granulomas are seen in certain chronic inflammation situations. There are clusters of macrophages, which have stuck tightly together, typically to wall something off. Granulomas can form with foreign bodies such as aspirated food, toxocara, silicone injections, and splinters. This discussion, demonstrates the extraordinary breadth of the causes, mechanisms, and treatment (or lack thereof) for inflammation. It establishes that it is not reasonable to accept any agent for treatment and prevention of inflammation generally. For example, rheumatoid arthritis remains a clinical entity of unknown etiology, Gripenberg, pg. 85. (Gripenberg, M, Scand. J. Rheumatology, Vol. 10 (2) 1981, 85-91). Applicant's disclosure does not enable one of ordinary skill in the art to make or

Art Unit: 1626

use the claimed invention within the entire scope of the diseases listed above. There is no compound, let alone entire classes of compounds, that can reverse, alleviate, prolong the progression of, prevent, or treat the various and divergent diseases listed above, as claimed.

The Amount of Direction / Guidance Present and the Presence or Absence of Working Examples

The only direction or guidance present in the instant specification is the explanation of inflammation in general and the binding assay data for eosinophils. The examples given are for asthma and rhinitis, both of which are enabled for the treatment, but not prevention. The specification does not contain any evidentiary support that these compounds, or their obvious variants, would be able to treat **and** prevent the plethora of inflammatory diseases. Furthermore, there are no working examples to support the treatment and/or prevention of the instantly claimed disorders.

The breadth of the claims

The claims are drawn to a method of treating (and preventing as implied by “susceptible to”) the genus of inflammatory conditions. Note one compound, let alone a genus of compounds, could possibly be effective for the prevention (reversal, alleviation, prolongation, progression) and treatment of the entire instantly claimed genus.

The level of the skill in the art

The level of skill in the art is high. However, due to the unpredictability in the

Art Unit: 1626

pharmaceutical art, it is noted that each embodiment of the inventions is required to be individually assessed for physiological activity by in vitro and in vivo screening to determine which compound exhibit the desired pharmacological activity and which diseases would benefit from this activity.

Thus, the specification fails to provide sufficient support of the broad use of the compound of the instant claims for the treatment or prevention of the genus of inflammatory condition, as a result necessitating one of skill to perform an exhaustive search for which diseases can be treated or prevented by what compounds of the instant claims in order to practice the claimed invention.

The quantity of experimentation needed

The quantity of experimentation needed is undue experimentation. One of skill in the art would need to determine what inflammatory conditions would be benefited (treated or prevented) by the compounds and compositions of Formula I and would furthermore have to determine which of the claimed compounds would provide treatment or prevention of which disease.

Thus, factors such as "sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the instantly claimed methods. In view of the breadth of the claim, the chemical nature of the invention, and the lack of working examples regarding the activity of the claimed compounds, one having ordinary skill

Art Unit: 1626

in the art would have to undergo an undue amount of experimentation to use the invention commensurate in scope with the claims.

Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001, states that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which diseases can be treated or prevented by the compound encompassed in the instant claims, with no assurance of success.

(Second Paragraph)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Regarding claim 4, the phrase "about" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "about"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05. The word "about" implies that n can be somewhere around 2, and therefore, it can be above or below. If it is above, is it above 2.2, and therefore no longer limiting instant claim 1. If it is below, is it below 0.8, and therefore no longer limiting instant claim 1. Appropriate correction is suggested.

Art Unit: 1626

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
7. Claims 1-10, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ancliff et al. (WO 02/26723) in view of Berge et al. [Berge, Stephen M., *Pharmaceutical Salts*, Journal of Pharmaceutical Sciences, 66(1) (1977) 1-19.]

Instant claims 1-4 are drawn to a compound of the formula (I) and its besylate salt. Ancliff et al., teaches a compound of the formula (I) (page 49, example 54) and its hydrochloride salt (page 59, example 124). This reference does not disclose the besylate salt of the instantly claimed compound of formula (I). Instant claim 5 is drawn to a dihydrate form of the instantly claimed compounds. Ancliff et al., discloses the production of hydrates and solvates on pages 14 and 25, respectively. Ancliff et al., describes the production of the hydrated form of 4-({[(2S)-4-(3,4-dichlorobenzyl)morpholin-2-yl]methyl}amino)carbonyl]amino}methyl)benzamide

Art Unit: 1626

benzenesulfonate in example 124, page 59. Instant claim 6 is drawn to a process for the preparation of a compound of formula (I) as described on page 49, example 54. The hydrochloride salt is described on page 59, example 124. Instant claim 7 is drawn to a compound of formula (I) for use with inflammatory conditions, as described by Ancliff et al., in pages 1, 2, and 24. Instant claim 8 is drawn to a method of manufacture of a medicament in a pharmaceutical composition, as described on page 24, lines 25 to 30. Instant claim 9 is drawn to a method of treatment of an inflammatory condition, as described on pages 1, 2, and 24. Instant claim 10 is drawn to a pharmaceutical composition, as described on page 25, paragraph 1. Instant claims 14 and 15 are drawn to a method of treatment of instant claim 9 wherein the inflammatory conditions are asthma and rhinitis, as disclosed by Ancliff et al., on page 24, line 25. As discussed above, this reference does not disclose the besylate salt of the instantly claimed compound of formula (I); however, it discloses the hydrochloride salt.

Berge et al., is a review article that discloses various useful pharmaceutical salts and their pharmacological effects. As evidenced by Table 1 on page 2, both the hydrochloride salt (as described in Ancliff et al.) and the benzenesulfonate salt (as instantly claimed) are FDA-Approved Commercially Marketed Salts. It would be obvious, from the Berge reference, for one of ordinary skill in the art, having knowledge of one existing pharmaceutically acceptable salt, to try to produce another one successfully.

KSR v. Teleflex, 127 S.Ct. 1727, 1740 (2007)(quoting Sakraida v. A.G. Pro, 425 U.S. 273, 282 (1976). “[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious”, the relevant question is “whether the improvement is more than the predictable use of prior art elements according to their established functions.” (Id.). Addressing

Art Unit: 1626

the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” KSR v. Teleflex, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that “[a] person of ordinary skill is... a person of ordinary creativity, not an automaton.” Id. at 1742.

In KSR v. Teleflex, 82 USPQ2d 1385, 1397 (U.S. 2007), the Supreme Court has held that when there is market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person has good reason to pursue known options within his or her technical grasp. Under these conditions, “obviousness to try” such options is permissible. In this instance, a market pressure exists in the medical/pharmaceutical industries to treat inflammatory conditions such as asthma and rhinitis. Accordingly, it would have been obvious to try the finite number of pharmaceutically acceptable salts as evidenced on page 2, Table 1, of Berge in order to pursue other known options within technical grasp and produce compounds and their salts for the same quoted purpose.

Thus, the instant claims are *prima facie* obvious.

Conclusion

8. No claims are allowed.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samantha Shterengarts whose telephone number is (571)270-5316. The examiner can normally be reached on Monday thru Thursday 9-6pm.

Art Unit: 1626

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samantha L. Shterengarts/
Examiner, Art Unit 1626

/Kamal A Saeed, Ph.D./
Primary Examiner, Art Unit 1626